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ARNOLD SCHWARZENEGGER
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Date: August 31, 2009

N.L.: 04-0509
Index: Benefits
(Supercedes N.L.: 11-1006)

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE
CHILDREN'S MEDICAL SERVICES (CMS) BRANCH STAFF

SUBJECT: PALIVIZUMAB (SYNAGIS™)

I. PURPOSE

The purpose of this numbered letter, which supercedes N.L.:11-1006, is to update CCS policy regarding the authorization of Palivizumab in conformance with the revised recommendations for its use published in the American Academy of Pediatrics (AAP) 2009 Red Book (28th edition) regarding immunoprophylaxis of Respiratory Syncytial Virus (RSV). Effective the date of this letter, the policy identified below supercedes the policy promulgated in N.L.:11-1006.

II. BACKGROUND

Palivizumab (trade name Synagis) is a humanized monoclonal antibody produced by recombinant DNA technology licensed by the Federal Drug Administration (FDA) and indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Typically, November through April is considered RSV season. Immunoprophylaxis against RSV is usually initiated at the beginning of November, and the last dose is administered at the beginning of March, providing protection into April.

In September 2003, the FDA granted approval to expand the product label for the use of Palivizumab to young children with hemodynamically significant congenital heart disease. In October 2003, the AAP issued a Policy Statement (<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;112/6/1442.pdf>) which was a revision of the 1998 policy. In 2006, the AAP Red Book, 27th edition, included revised recommendations for the use of Palivizumab, and in 2009, these recommendations have been revised again in the AAP Red Book, 28th edition.

III. POLICY

- A. Palivizumab is a benefit for CCS clients, regardless of the eligible medical condition, who also meet one of the following criteria:
1. Children 24 months of age or younger at the start of RSV season with Chronic Lung Disease (CLD) requiring medical treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid, or other treatment) within six months before the anticipated start of the RSV season.
 2. Infants born at 28 weeks of gestation or earlier and who are less than 12 months of age at the start of RSV season.
 3. Infants born at 29 to 32 weeks of gestation who are less than six months of age at the start of RSV season.
 4. Infants born at 32 weeks to less than 35 weeks of gestation and who are born less than 3 months before the onset or during the RSV season and for whom at least one of the following risk factors is present:
 - a. infant attends child care*, or
 - b. infant has a sibling less than 5 years old or there is a child less than 5 years old living permanently in the household.

*Child care is defined as a home or facility where care is provided for any number of infants or young toddlers.

5. Children who are 24 months of age or younger at the start of RSV season with cyanotic or acyanotic CHD and the request for service is from the CCS approved Cardiac Special Care Center (SCC) or a cardiologist from a CCS approved Cardiac SCC, or the request is from a CCS approved pediatrician authorized in conjunction with a CCS approved Cardiac SCC or a CCS approved cardiologist from the Cardiac SCC. Note: The approved cardiologist must be in agreement, if the pediatrician is requesting Palivizumab.

6. Children with severe immunodeficiencies (e.g., severe combined immunodeficiency, acquired immunodeficiency syndrome, transplant recipients, or children who are immunocompromised due to chemotherapy) and the request for service is from a CCS approved Infectious Disease and Immunologic Disorder SCC, Transplant SCC, Hematology/Oncology SCC, or the request is from a CCS approved pediatrician authorized in conjunction with one of these CCS approved SCCs. Note: The approved SCC must be in agreement, if the pediatrician is requesting Palivizumab.
 7. Infants born before 35 weeks of gestation and who are in the first year of life who have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions.
 8. The CCS County or Regional Office Medical Consultant, after consulting with the CCS approved pediatric subspecialist may determine that an exception to criteria III.A.1-7 is medically justified. An example of an exception is clinical evidence, supported by medical literature, that the patient has a CCS medically eligible condition that would likely cause significant cardiopulmonary deterioration and hospitalization if the patient developed a RSV infection.
- B. For children who meet criteria III.A.1, 2, 3, 4 and 7, the request for service shall be from the CCS authorized pediatric subspecialist or CCS approved SCC; or the request shall be from a CCS approved pediatrician authorized in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC. Note: The approved pediatric subspecialist or SCC must be in agreement, if the pediatrician is requesting Palivizumab.
- C. Premature infants who are currently only eligible for diagnostic services through the high-risk infant follow-up program are not eligible for authorization of Palivizumab.
- D. Palivizumab must be authorized as requested through the end of RSV season except for the infants specified in III.A.4. The infants specified in III.A.4 receive a maximum of 3 doses.
- E. If an infant or child experiences a breakthrough RSV infection, monthly prophylaxis should continue until a maximum of 3 doses have been administered to infants in the 32 to less than 35 weeks' gestation group or until a maximum of 5 doses for infants described in III.A.1-3, and 5-7.

- F. Though it is preferred that the care of a CCS eligible infant/child be authorized to a CCS approved pediatrician in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC, there are circumstances when there is no CCS approved pediatrician in an infant's/child's area of residence. In these circumstances references to "CCS approved pediatricians" in III.A.5 and 6, and in III.B., may be substituted with "CCS approved family practitioners". These family practitioners also need to be authorized in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC.

IV. POLICY IMPLEMENTATION

Authorizations:

- A. Palivizumab requires separate authorization for outpatient administration. Palivizumab injections are administered monthly and may be authorized for up to a total of five injections over a five-month period of time (unless there is documentation by the requesting physician of longer need due to a lengthier RSV season). The exception is the infants born between 32 and 35 weeks gestation who will receive a maximum of three injections of Palivizumab.
- B. Palivizumab does not need a separate authorization for inpatient administration.
- C. Palivizumab is a Medi-Cal benefit. Please refer to "This Computes!" for the current method of authorizing Palivizumab.
- D. *Expedite Palivizumab authorizations to help ensure prompt initiation of protection from RSV for the infant/child and to prevent a lapse in protection, especially for the infant who will frequently receive the first injection in the hospital prior to discharge.*

If you have any questions regarding this numbered letter, please contact your state regional office medical consultant.

Original Signed by Harvey Fry for Luis R. Rico

Luis R. Rico, Acting Chief
Children's Medical Services Branch